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## 2015 Exploration Medical Capability Standing Review Panel

Research Plan Review for:

*The Risk of Adverse Health Outcomes & Decrements in Performance due to Inflight Medical Conditions*

### Final Report

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#### I. Executive Summary and Overall Evaluation

The 2015 Exploration Medical Capability (ExMC) Standing Review Panel (from here on referred to as the SRP) met for a site visit in Houston, TX on December 10 - 11, 2015. The SRP reviewed the updated research plan for the Risk of Adverse Health Outcomes and Decrements in Performance due to Inflight Medical Conditions (ExMC Risk).

In general, the SRP is pleased with the progress of the research plan and the logical, chronological, and manageable way the Gaps are addressed. The ExMC Research Plan presented to the SRP in December 2015 fulfilled this Element's responsibility to provide three types of deliverables: 1) knowledge about medical issues of concern for exploration missions; 2) medical informatics tools; and 3) medical technologies. This ExMC Research Plan appears to be more tightly coupled to engineering systems development than any plan this SRP has previously evaluated and that is a very positive feature. Formally dividing ExMC's work into operations research, information resources, and technology development allows for closer interactions between clinicians and engineers in designing future medical and flight systems.

The ExMC Element has identified two paradigms for space exploration: 1) the low Earth orbit (LEO) paradigm and 2) the outside of LEO paradigm. The current plan is premised on the exploration paradigm, in which the crew most likely would have limited access to regular resupply and evacuation. Thus, the current plan appropriately accounts for the need for autonomy in delivering event-driven care in deep space where communication with Earth will be delayed or absent. Given that other organizations are currently focusing on the LEO paradigm, the SRP agrees with the research plan's emphasis on risks beyond LEO.

The updated ExMC Research Plan has consolidated 24 open Gaps in medical risk (out of 33 previously identified Gaps, 24 are currently open and nine are now closed) into 13 new Gaps. Among the revised set of 13 Gaps in medical risk, seven are existing Gaps and six are new Gaps. This new classification of Gaps makes the current plan more logical and easier to understand. Each of the 13 new Gaps of medical risk can now be thought of as falling into one of three categories: 1) operational Gaps (Med-01 – Med-06; 2) information resource Gaps (Med-07 – Med-10); and 3) technology Gaps (Med-11 – Med-13). These three Gap categories focus, respectively, on policies, software, and hardware.

The ExMC Element research responsibilities now include the previous ExMC Risks and three additional Risks. These include: 1) The Risk of Bone Fractures Due to Spaceflight-Induced Changes in Bone; 2) The Risk of Renal Stone Formation; and 3) The Risk of Ineffective or Toxic Medications Due to Long Term Storage. The SRP agrees that the new Risks are relevant to the mission of the ExMC Element.

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Finally, incorporating the consideration of astronaut health and performance in the vehicle design is essential. The current research plan not only accounts for human factors research, but for the first time specifies that the design of medical systems should be integrated into the vehicle design. The SRP commends the ExMC Element for working with other stakeholders to develop a user-friendly vehicle-based medical system.

The following is a summary of the general comments and recommendations by the SRP:

- The SRP agrees with the guiding principles of the ExMC Element as articulated through the new Concept of Operations, which allows for explicit tradeoffs of mass, volume, weight, risk, and capability.
- The SRP recommends a clearer articulation of the policies and procedures used to transfer knowledge and tools developed by the ExMC Element to NASA operations.
- The SRP notes that although the exploration paradigm requires functioning in an environment containing limited resources, data handling capability is growing rapidly which can be an opportunity for achieving goals of the ExMC Element.
- The Concept of Operations, as specified into two computer models: 1) the Integrated Medical Model (IMM) and 2) the Medical Optimization Network for Space Telemedicine Resources (MONSTR), enables flexibility in identifying research needs and recommending medical capability. This will be important as medical knowledge about the health effects of space flight and medical device technology develops.
- The IMM is an important tool to forecast medical outcomes for inflight operations and medical impacts to missions. The IMM models the burden of risk for various conditions according to their: 1) likelihood in bins of increasing probability; and 2) consequences of the condition on mission health and performance in bins of increasing morbidity, given a specified diagnostic, treatment, and rehabilitation capability. For condition-specific risks this “risk modeling tool” allows for steps to be taken to decrease the risk burden. The likelihood of risky conditions occurring can be decreased (i.e., to avoid consequences) by focused selection, screening, prevention, vehicle design standards, and mission architecture. The morbidity consequences of risky conditions can be decreased by proper application of medical capability (i.e., to minimize consequences) with appropriate diagnosis, treatment, chronic management, and rehabilitation. Both processes decrease the likelihood and consequences of risky conditions and therefore can decrease their risk burden. The methods for decreasing both likelihood and consequences of risks derive from five systems, including: 1) medical support; 2) technology development; 3) training; 4) medical decision support software; and 5) integration of medical support with vehicle design and Environmental Control & Life Support System Maturation Teams. The SRP thinks this approach is innovative for both quantifying and reducing risk.
- The MONSTR, which is in an early stage of development, is a modeling tool that enables analysis of trade-offs among medications, technologies, and skill sets to achieve the

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greatest capability for a space mission. The tool incorporates data from the IMM as to the likelihood of each expected condition in the IMM list and as well as the resources needed for each condition and how critically they are needed for each condition. An optimal set of tools to bring into space can then be prioritized in this model, which was developed by NASA. The MONSTR output is based on assumptions from: 1) the IMM about the likelihood and consequence of conditions given specific medical capabilities; and 2) an analysis of terrestrial standard of care related to the criticality of resources for treating each condition. This model can provide measures of utility of each piece of medical technology (including drugs and devices). These measures of utility then support decisions about risk tradeoffs given the mass, volume, and power available to the exploration medical capability.

- Given the limited amount of resources that can be transported into space, the SRP believes that the MONSTR model could be very important for selecting the most useful medical technologies and training for space missions.
- Together, the IMM and the MONSTR provide for specific, measurable, actionable, and transparent analysis of medical conditions, risks of these conditions, and risk tradeoffs associated with carrying various medical technologies (drugs, devices and equipment) into space. The goal of using these programs is to select astronauts and equip vehicles to minimize risk. The IMM and the MONSTR provide a foundation for organizing the ExMC's work. They provide resilience for future changes in medical knowledge, medical technology, and mission priorities. Therefore, the IMM and the MONSTR should be a high priority for the ExMC Element, and the SRP recommends that additional resources be devoted to developing these computer models.
- The SRP further recommends the ExMC Element consider developing a mathematical model that will assist crew members to make decisions about how to use consumable medical supplies while in-flight.
- There is a gap in astronaut selection and it needs to be articulated. The IMM estimates risks for conditions not frequently seen in space using published information from a wide variety of sources, such as actuarial tables published by the Centers for Disease Control. These sources can only approximate the risks faced by astronauts. Astronaut selection (i.e., "prevention") is a key component of the exploration medical capability, and a more systematic approach is needed to model the effect of astronaut selection on exploration risk. For example, the IMM should be enhanced to address the questions like these: What is the effect (change in risk) of astronaut selection requiring higher preflight bone densities compared with lower preflight densities? What is the change in risk associated with allowing a second-degree family history of cardiovascular disease (given sex, age, and other cardiovascular disease (CVD) risk factors) compared with not allowing this family history? Where the data needed to model these questions is available in the medical literature, and then the resources should be provided to review these data and integrate the data into the IMM.

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- The SRP suggests that NASA seek input from astronaut-physicians who have worked in space, to help make these decisions about what type of medical care should be delivered in space.
  - The Concept of Operations and enhancements to the associated mathematical models will enable improved priority setting for future research (e.g., pharmacology and training).

## **II. Critique of Gaps and Tasks for the Risk of Adverse Health Outcomes & Decrements in Performance due to Inflight Medical Conditions**

- A. *Have the proper Gaps been identified to mitigate the Risk?*
  - a. *Are all the Gaps relevant?*
  - b. *Are any Gaps missing?*
- B. *Have the gap targets for closure been stated in such a way that they are measureable and closeable?*
  - a. *Is the research strategy appropriate to close the Gaps?*
- C. *Have the proper Tasks been identified to fill the Gaps?*
  - a. *Are the Tasks relevant?*
  - b. *Are there any additional research areas or approaches that should be considered?*
  - c. *If a Task is completed, please comment on whether the findings contribute to addressing or closing the Gap.*
- D. *If a Gap has been closed, does the rationale for Gap closure provide the appropriate evidence to support the closure?*

### **Gaps and Tasks:**

A proper set of Gaps is presented in the ExMC Risk Research Plan. The updated research plan incorporates (in addition to traditional risks to health and performance) renal, bone, and pharmacy Risks, which are appropriate topics for the ExMC Element to address.

### **Med-01: We do not have a concept of operations for medical care during exploration missions.**

- The SRP recommends rewording the Gap title to more explicitly state its integrative function of the other ExMC Gaps: We do not have a concept of operations that integrates research activities related to the various aspects of exploration medical capability including operations research, information resources, and technology development.
- The SRP commends the ExMC Element for defining a Concept of Operations (conceptual model) that integrates research needs related to conditions, risks, technology, skills, information, and capabilities.
- This Gap addresses which medical conditions will receive care and the specific methods for delivering care. The decision will be based, in part, on constraints resulting from lack of resupply or evacuation, limited availability of telemedicine care, and the well-known limitations on mass, volume, and power. For example, should astronaut selection require

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removing the appendix preflight if it is determined that appendectomy in space will not be feasible?

- The Concept of Operations enhances communication about the ExMC Element's gaps, tasks, and goals.
- The Concept of Operations provides a powerful tool in laying out research gaps in a manner that is logical, integrative, and well phased.
- The framework is flexible in enabling the addition, in the future, of new knowledge and technological innovation.
- Mapping of the Concept of Operations to the IMM is concrete and transparent.
- By design, the Med-01 Gap will remain open until all other ExMC Gaps (below) close.
- The following tasks were developed under the previous organization of the ExMC's research plan, which has since undergone major reconsideration. Those that are closed were appropriately closed. Those that remain open are appropriate. The planned tasks are appropriate, although select medical conditions could be reassigned to Med-12.

Tasks:

- ExMC Tech Watch – PI: Michael Krihak, Ph.D. – NASA Ames Research Center
- Study of the impact of long-term space travel on the astronaut's microbiome (SHFH) – PI: Hernan Lorenzi, Ph.D. – J Craig Venter Institute
- Improving CV Risk Prediction -- Biomarkers and Beyond, Implications for Astronaut Selection and Monitoring During Prolonged Spaceflight (CV BIOMARKERS / DE LEMOS / ACTIVE) – PI: James Andrew de Lemos, M.D., The University of Texas Southwestern Medical Center at Dallas
- Human Research Wiki (Archived) – Completed Task
- Cardiovascular Imaging and Strategies to Mitigate the Risk for Cardiac Events in Astronauts During Prolonged Spaceflight (Cardiac Risk-Imaging -- Levine, Completed) (HHC) – Completed Task
- Evaluating the Spaceflight Infectious Disease Risk Potential of Pathogenic and Commensal microorganisms using *Caenorhabditis elegans* as a Human Surrogate Model for Infection (SHFH) – Completed Task
- Determine requirements for inflight periodic health status exams based on Exploration Medical Condition List – Completed Task
- Data Mining/Identification of characteristics associated with susceptibility to hypobaric environments – Completed Task
- Development of Methods/Technologies for Dental Conditions – Completed Task
- Research Treatment of Relevant Medical Conditions in Remote, Resource Poor Environments – Completed Task
- ExMC Support of Medical Scenarios for the Autonomous Mission Operation (AMO) Test – Completed Task

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- Development of Capability to Protect Medications in Spaceflight (Archived) – Completed Task
  - Data Sharing Activity to Gather Evidence for Impaired Healing Risk (HHC) – Planned Task

**Med-02: We do not have the capability to provide a safe and effective pharmacy for exploration missions.**

- The SRP identified this Gap as being in the top tier of priority because pharmacy is a key modality for definitive treatment and is useful for differential diagnosis and presumptive treatment.
- The main issue in this Gap is how to provide a safe and effective pharmacy given two questions that must be answered: 1) which drugs should be brought into space and for what indications; and 2) how can these drugs be kept safe from degradation to become ineffective and possibly from toxicity in case the product expiration date while a mission is still in progress and resupply is not possible?
- SRP recommends that the pharmacology stability Risk should be incorporated into this Gap.
- Given the research nature of exploration, it is important to clarify the human subject issues related to repackaging and other Food and Drug Administration (FDA) concerns. The SRP felt that permission to possibly provide drugs off label and/or past their expiration date was not clearly presented by the ExMC. Such permission to possibly put astronauts at risk was not clearly described as either a NASA operational requirement per the Aerospace Medical Board or as an FDA-governed Institutional Review Board (IRB)-approved research process (where benefits outweigh risks) with informed consent. Further clarification and closure of this issue was recommended.
- Although the pharmacokinetics/pharmacodynamics (PK/PD) concern is still under the Human Health Countermeasures (HHC) Element, the SRP believes that it is critical that the ExMC Element interfaces with them and stay abreast of the status of the research. The SRP suggests four additional questions for the ExMC Element to work on: 1) Which drugs are needed in space missions and for which conditions? 2) What are the storage capabilities (including mass/volume? 3) What are the repackaging constraints? 4) Which adverse events and side effects occur from drugs that are used in space? Key characteristics of drugs that relate to their packaging, storage, and use during a mission are not well integrated. The SRP recommends use (or development) of a pharmacy database to synthesize this knowledge and improve knowledge-sharing across Human Research Program (HRP) Elements.
- The Raman Spectroscopy Analyzer project and the 3D printing project should both undergo further testing. These are promising approaches to ensuring safe and effective drugs in the space environment.



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Task:

- Medication Stability Analysis: Device (Pharm 01) – PI: TBD
- Retrospective Analysis of Medication Usage During Long Duration Spaceflight (Pharm 01) – PI: Virginia Wotring, Ph.D., NSBRI
- Dose Tracker Application for Monitoring Crew Medication Usage, Symptoms and Adverse Effects During Missions (Pharm 01) – PI: Virginia Wotring, Ph.D., NSBRI
- Ground Stability Testing (Pharm 02) – Planned Task
- Medication Stability Analysis: Method (Pharm 02) – Planned Task

**Med-03: We do not know how to apply personalized medicine effectively to reduce health risk for a selected crew.**

- The SRP notes that the term “personalized medicine” has been reconceived by the National Institutes of Health to a more specific term: “precision medicine” (<http://ghr.nlm.nih.gov/handbook/precisionmedicine/precisionvspersonalized>). Precision medicine uses big data and multiple types of physiological and genetic inputs to make predictions about the best selections of therapy. Although this is cutting edge medicine, the SRP thinks it may be too early to get involved.
- The SRP suggests the ExMC Element track/follow the work currently being done in the Advanced Environmental Health (Host Microbe) Project, specifically with respect to microbiome research, because the microbiome is one of the key environmental factors that drive genetic expression; can be altered by diet and drug exposures; and is itself a risk factor for diseases including infections and metabolic disease, among others. Knowledge of the microbiome is expanding rapidly.
- The SRP agreed with the ExMC Element that various types of omics information should be obtained as technologies for such collections become available. This information will facilitate development of a precision medicine database for each astronaut.
- The SRP previously recommended and recommends again that full body images of astronauts be obtained in order to establish a medical baseline data for each astronaut.
  - The SRP recommends also obtaining baseline genetic/genome for each astronaut to see what happens after long-term exposure to radiation.
  - This could be a possible new task or add this to the current baseline data that is already being collected from the astronauts.

No current tasks

**Med-04: We do not have a defined rehabilitation capability for injured or de-conditioned crew members during exploration missions.**

- The SRP agrees with the approach of rehabilitation as a key word in defining capability.

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- The new gaps are important specifically for inflight rehabilitation.
  - The SRP believes this Gap may require more study to define the inflight requirements and countermeasures and could be incorporated into the MONSTR.
  - This Gap deals with rehabilitation in microgravity and a better solution is needed operationally to achieve such rehabilitation.
  - The SRP applauds the goal of dual-use equipment for both rehabilitation and conditioning, as well as the potential identification by the ExMC Element of non-exercise technologies for rehabilitation.
  - The SRP agrees with how the 100 IMM conditions are now classified according to organ system rather than in alphabetical order, which was the case in the past.
  - The SRP recommends adding asthma/bronchospasm and muscle cramps to the IMM list.

Tasks:

- Risk of Intervertebral Disc Damage After Prolonged Spaceflight (HHC) – PI: Alan Hargens, Ph.D., University of California - San Diego
- Sonographic Astronaut Vertebral Examination (HHC) – PI: Scott Dulchavsky, M.D., Ph.D., Henry Ford Health System
- Development of capability to treat musculoskeletal injuries – Planned Task

**Med-05: We do not know how to train crew for medical decision making and medical skills to enable extended mission or autonomous operations.**

- The SRP agrees with how this is being addressed in the IMM model with respect to incorporating this knowledge into the medical decisions and skills. There is an emphasis on training methods in general rather than on a specific task that is the subject of the training.
- The ExMC Element distinguishes two types of training: 1) Procedures and 2) Medical decision making. The SRP agrees that the approach used to medical decision making will be critical to operational success.
- This Gap addresses the idea of autonomy without ground support very well.
- The SRP recommends that the ExMC Element seek input from an expert who is knowledgeable in adaptive or perceptual learning – novel way to educate crew members. This process should begin on the ground and utilize stored modules on the vehicle that can be accessed by crew members at any time, and/or as part of scheduled ongoing learning.

Tasks:



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- Clinical Outcome Metrics for Optimization of Robust Training – PI: Douglas Ebert, Ph.D., NASA Johnson Space Center
  - Assisted Medical Procedures – Completed Task
  - Integration of iRevive with the Lightweight Trauma Module – Completed Task
  - ExMC Support of Medical Scenarios for the Autonomous Mission Operation (AMO) Test – Completed Task
  - Medical training methods for exploration missions– Completed Task
  - Medical Proficiency Training (SHFH) – Completed Task
  - Data mining for telementoring studies and practices – Completed Task
  - Telemedicine Workshop – Completed Task
  - Air/Fluid Separation in a Syringe in a Microgravity Environment – Completed Task
  - Electronic Procedures for Crewed Missions Beyond Low Earth Orbit (LEO) (SHFH) – Planned Task
  - Evaluation of Task-Skill-Knowledge JIT techniques for medical and other emergency events (SHFH) – Planned Task
  - Advanced concepts for information integration and presentation (SHFH, Archived) – Planned Task

**Med-06: We do not know how to define medical planning or operational needs for ethical issues that may arise during exploration missions.**

- The SRP is concerned that Med-06 implicitly contains concepts related to planning for severe injuries and loss of crew life. The SRP recommends that treatment with palliative intent be explicitly planned as a medical capability in Med-07. Palliative care provides for the development and implementation of protocols to ease suffering and improve the quality of life for both the dying/disabled crew member and the rest of the crew. Ethical issues are separate from palliative care capabilities.
- With respect to medical ethics, one need is to train crew members to make ethical judgments to weigh the value of extraordinary medical treatment to one crew member that may place other crew members at increased risk. This could be an educational module (make astronauts and ground crew more comfortable with decision making using Ethics frameworks). Creation of scenarios for training the crew could be a new task under this Gap.
- The SRP recommends that a medical ethicist be engaged to help guide the articulation of relevant research questions.

No current tasks

**Med-07: We do not have the capability to comprehensively process medically-relevant information to support medical operations during exploration missions.**

- The SRP believes that it is important to continue the development of an agile health information system to process medically-relevant information inflight.

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- The Exploration Medical System Demonstration (EMSD) is an important tool to defining the medical capability for exploration missions.
  - As more information is gathered, the compatibility of data must be considered for all devices, both ground and in-flight.
    - Middleware can convert multiple inputs into a common language for transmission to Earth.
  - The SRP recommends that automatic physiological data uploading for astronauts be utilized to avoid incomplete compliance and/or entry errors.
  - The SRP agreed with the ExMC Element's plan to use an electronic medical record (EMR) that includes only medical information and no billing or administrative inputs to streamline use and not waste time.

Tasks:

- Biosensors for Medical System – PI: Bill Toscano, Ph.D., NASA Ames Research Center
- Medical Consumables Tracking – PI: John Zoldak, Ph.D., ZIN Technologies
- Exploration Medical System – Completed Task
- Middleware for Medical System – Completed Task
- Electronic Medical Records – Completed Task
- Dental for Medical System – Completed Task
- Assisted Medical Procedures – Completed Task
- Distributed System for Spaceflight Biomedical Support – Completed Task
- Exploration Medical System Demonstration (EMSD) Baseline Capability Evaluation using the Habitation Development Unit (HDU) – Completed Task
- ExMC Support of Medical Scenarios for the Autonomous Mission Operation (AMO) Test – Completed Task

**Med-08: We do not have quantified knowledge bases and modeling to estimate medical risk incurred on exploration missions.**

- The SRP encourages NASA to utilize modeling where ever possible:
  - Modeling allows prioritization of medical capabilities.
  - Modeling allows NASA to quantify risk (IMM) and prioritize resources (MONSTR).
- The IMM and MONSTR efforts are in the top tier of priority and should be moved forward quickly.
  - This type of modeling capability could address many of the issues that the ExMC Element will encounter.
  - The best case scenario and worst case scenario approach to modeling outcomes, provides an effective way to bound the issues.

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- The method used to incorporate lessons learned during the development of the IMM and the MONSTR was not clearly explained. These lessons should be used for future modeling efforts.
  - The SRP would like to see modeling used inflight (relevant to Gap Med-08 and Med-09).
  - The SRP thinks the current 8 – 12 week time required for the review process to accept new IMM modeling outputs is long.
    - The SRP suggests that the ExMC Element look at new methods to speed up the output validation/review process.
  - The SRP understands that the IMM forecasts outcomes only for inflight operations and not post-mission medical consequences.
    - The SRP recommends considering a postflight medical consequences modeling effort as well.
  - The Crew Health Index (CHI) is an appropriate measure (defined as proportion of mission time not lost to medical events).

Tasks:

- Integrated Medical Model (IMM) – PI: Douglas Butler, NASA Johnson Space Center
- Integrated Medical Model - Renal Stone Module – PI: Jerry Myers, Ph.D., NASA Glenn Research Center
- Integrated Medical Model - Bone Module – PI: TBD
- Metric Development to Quantify Change in Mission Risk Due to a Physician-Trained Crew Medical Officer – PI: Jerry Myers, Ph.D., NASA Glenn Research Center
- Clinical Outcome Metrics for Optimization of Robust Training – PI: Douglas Ebert, Ph.D., NASA Johnson Space Center
- Integrated Medical Model - Chest Injury Module – Completed Task
- Integrated Medical Model - Head Injury Module – Completed Task
- Integrated Medical Model - Abdominal Injury Module – Completed Task
- Integrated Medical Model - Bayesian Analysis – Completed Task
- Integrated Medical Model - Neck Injury Module – Completed Task
- Integrated Medical Model - Sleep Module – Completed Task
- Intuitive Ultrasound Catalog for Autonomous Medical Care – Completed Task
- ExMC Support of Medical Scenarios for the Autonomous Mission Operation (AMO) Test – Completed Task
- Quantify impacts of physician training on medical task performance – Terminated Task

**Med-09: We do not have the capability to predict estimated medical risk posture during exploration missions based on current crew health and resources.**

- The SRP recommends rewording the Gap title for clarity to: We do not have the capability to predict the crew's increasing medical risk during the course of the mission,

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as medical resources are used and crew health declines.

- The SRP agrees that an accurate inventory of consumables is important and that research should be continued until this Gap is closed.
- The SRP recommends that a mathematical model be developed to help the crew/ground control appropriately ration consumable medical resources based on crew health and remaining stocks.
- The SRP suggest that the ExMC Element explore the use of smart pills (electronically tagged) once they are approved by the FDA. They may be useful in tracking drug delivery.
- The Medical Consumables task (below) is relevant and could be tested in a ground analog, if implementation questions remain.

Tasks:

- Medical Consumables Tracking – PI: John Zolda, Ph.D., ZIN Technologies

**Med-10: We do not have the capability to provide computed medical decision support during exploration missions.**

- Computerized clinical decision support can incorporate sensor data, images, history, exercise capabilities, and environmental data. This software should be used as an integral component of the electronic medical record. Such software will be needed on trips into deep space where ground support will take too long to be a sole source of useful advice for acute problems.
- Decision support software already exists and evolves as medical knowledge expands and new diagnostic and treatment modalities become available.
- To help the crew use computerized decision support, we recommend consideration of software designed with high quality User Interface/User Experience (UI/UX) programs.
- The SRP recommends incorporating natural language recognition/analysis into decision support, such as Amazon Echo.

Tasks:

- Integration of iRevive with the Lightweight Trauma Module – Completed Task
- ExMC Support of Medical Scenarios for the Autonomous Mission Operation (AMO) Test – Completed Task

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**Med-11: We do not have the capability to minimize medical system resource utilization during exploration missions.**

- The SRP was impressed by this effort to maximize limited resources by repurposing tools and other resources to allow conservation of mass, volume, and energy. This Gap is intended to use technologies intended for medical purposes for non-medical purposes and vice versa. An example is to use an x-ray device to also assess performance of an electronics module.
- This Gap is not expected to close because new technologies are constantly being developed and some of them might be suitable for cross-cutting purposes that are both medical and non-medical.
- The ExMC no longer has a Tech Watch under this Gap, and the SRP believes that a replacement is needed.

No current tasks

**Med-12: We do not have the capability to mitigate select medical conditions.**

- The SRP is pleased that the ExMC Element has moved previous research risks into operations, particularly the bone fracture risk, the renal stone risk and the stability risk.
- This Gap includes specific risks that have been recently assigned to it (bone disease and renal stones), as well as legacy gaps including musculoskeletal injuries and exposure to lunar dust.
- The SRP supports that this Gap will utilize dual-use devices for both diagnoses and treatment (e.g., x-ray).
- The SRP is pleased with the work the ExMC Element is doing with General Electric on a flexible ultrasound technology that can reposition renal stones (which occur more frequently in space because of microgravity, dehydration, and hypercalciuria from bone mineral loss) when they are stuck and painful and also detect small stones by way of a twinkling artifact.
- The SRP is pleased that the ExMC Element is using the ultrasound technology to detect bone mineral loss, and provide therapy for fractures and musculoskeletal back pain.

Tasks:

- Portable Quantitative Ultrasound with DXA/QCT and FEA Integration for Human Longitudinal Critical Bone Quality Assessment – PI: Yi-Xian Qin, Ph.D., SUNY- The State University of New York
- Flexible Ultrasound System for Quantitative Diagnosis and Therapeutic Ultrasound – PI: William Thompson, Ph.D., NASA Glenn Research Center

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- Risk of Intervertebral Disc Damage After Prolonged Spaceflight (HHC) – PI: J Alan Hargens, Ph.D., University of California - San Diego
  - Sonographic Astronaut Vertebral Examination (HHC) – PI: Scott Dulchavsky, M.D., Ph.D., Henry Ford Health System
  - Prevention of Renal Stone Complications in Space Exploration – PI: Michael Bailey, Ph.D., University of Washington
  - Integrated Medical Model - Renal Stone Module – PI: Jerry Myers, Ph.D., NASA Glenn Research Center
  - Wearable, Sustained Acoustic Medicine for Back Pain – PI: TBD
  - Combined Scanning Confocal Ultrasound Diagnostic and Treatment System for Bone Quality Assessment and Fracture Healing – Completed Task
  - Ultrasound Fracture Diagnosis in Space – Completed Task
  - LADTAG Lunar Dust Health Standard (SHFH) – Completed Task
  - Clearance of Particles Depositing in the Human Lung in Low-Gravity (SHFH) – Completed Task
  - Improving Kidney Stone Detection in Space Analogs – Completed Task
  - Development of capability to treat musculoskeletal injuries – Planned Task
  - Development of capability to treat bone fractures – Planned Task
  - Development of Capability to Monitor and Treat Disease Caused by Dust Exposure During Exploration Missions – Planned Task

**Med-13: We do not have the capability to implement medical resources that enhance operational innovation for medical needs.**

- This Gap describes 10 capabilities to provide, generate, prevent and other processes. These capabilities all describe enabling technologies. Therefore the SRP suggests that the Gap title include “implementing technologies for medical needs”.
- Dual use devices and solutions are valuable for resource management (crew time, energy, weight, etc.) incorporating technologies with multiple functions.
- Unlike Gap Med-11, which promotes development of cross-cutting technologies for both medical and nonmedical uses, Gap Med-13 promotes technologies for a variety of specific medical conditions. The SRP supports the utilization of dual use technologies for both gaps.

***Tasks:***

- Oxygen Delivery System – PI: Sandra Olson, Ph.D., NASA Glenn Research Center
- Exploration Laboratory Analysis – PI: Michael Krihak, Ph.D. – NASA Ames Research Center
- Cell Phone-based Lateral Flow Assay for Blood Biomarker Detection – PI: Manal Beshay, Ph.D., Intelligent Optical Systems, Inc.
- IVGEN PostFlight Analysis – PI: John McQuillen, Ph.D., NASA Glenn Research Center
- Biosensors for Medical System – PI: Bill Toscano, Ph.D., NASA Ames Research Center



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Flexible Ultrasound System – PI: William Thompson, Ph.D., NASA Glenn Research Center

- Wideband Single Crystal Transducer for Bone Characterization – PI: Kevin Snook, Ph.D., TRS Ceramics, Inc.
- Portable Quantitative Ultrasound with DXA/QCT and FEA Integration for Human Longitudinal Critical Bone Quality Assessment] – PI: Yi-Xian Qin, Ph.D., SUNY- The State University of New York
- Flexible Ultrasound System for Quantitative Diagnosis and Therapeutic Ultrasound PI: William Thompson, Ph.D., NASA Glenn Research Center
- Non-Invasive Monitoring of Intracranial Pressure (ICP) with Volumetric Ophthalmic Ultrasound [ULTRASOUND ICP/DENTINGER/ACTIVE] (HHC) – PI: Aaron Dentinger, Ph.D., NGE Global Research
- Non-Invasive Monitoring of Intracranial Pressure with Volumetric Ophthalmic Ultrasound: Integration with NASA's Flexible Ultrasound System (FUS) – PI: Aaron Dentinger, Ph.D., NGE Global Research
- JAXA Auscultation Data Review – PI: Douglas Ebert, Ph.D., NASA Johnson Space Center
- Combined Scanning Confocal Ultrasound Diagnostic and Treatment System for Bone Quality Assessment and Fracture Healing – Completed Task
- Intuitive Ultrasound Catalog for Autonomous Medical Care – Completed Task
- Ultrasound Fracture Diagnosis in Space – Completed Task
- Validation of On-Orbit Methodology for the Assessment of Cardiac Function and Changes in the Circulating Volume Using Ultrasound and Braslet-M Occlusion Cuffs, SDTO 17011 U/R (Braslet-M -- Duncan, Completed) – Completed Task
- Multi-Use Near-Infrared Spectroscopy System for Spaceflight Health Applications – Completed Task
- First Clinical Test of Feasibility of Ultrasound to Reposition Kidney Stones – Completed Task
- Development of Pressure Swing Adsorption Technology for Spaceflight Medical Oxygen Concentrators – Completed Task
- Evaluation of Oxygen Concentrators at Altitude – Completed Task
- Portable Cathode-Air-Vapor-Feed Electrochemical Medical Oxygen Concentrator – Completed Task
- Lightweight Trauma Module – Completed Task
- In-flight Blood Analysis Technology for Astronaut Health Monitoring – Completed Task
- Nanoscale Test Strips for Multiplexed Blood Analysis – Completed Task
- Reusable Handheld Electrolytes and Lab Technology for Humans – Completed Task
- IntraVenous Fluid GENeration for Exploration Missions – Completed Task
- Smart Therapeutic Ultrasound Device for Mission-Critical Medical Care – Completed Task
- ExMC Support of Medical Scenarios for the Autonomous Mission Operation (AMO) Test – Completed Task
- Lightweight, Wearable Metal Rubber-Textile Sensor for In-Situ Lunar Autonomous Health Monitoring – Completed Task

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- Lunar Health Monitor: A Wearable System to Monitor Astronaut Health Status – Completed Task
  - Wearable Health Monitoring Systems – Completed Task
  - Biomedical Sensors Requirements for Extravehicular Activities – Completed Task
  - Intraosseous (IO) Access Device Demonstration – Completed Task
  - Development of Medical Suction Technology – Planned Task
  - Development of Capability for Algorithm-based Fluid Resuscitation – Planned Task
  - Development of Capability to Irrigate the Eye – Planned Task
  - Development of Capability to Sterilize Medical Equipment in Spaceflight – Planned Task
  - Spaceflight Injectable Delivery System – Terminated Task
  - Review and Assess State of Knowledge Regarding the Acute or Chronic Cardiovascular Toxicity of Mineral Dusts (SHFH, Archived) – Terminated Task

### **III. Discussion on the strengths and weaknesses of the IRP and identify remedies for the weaknesses, including answering these questions:**

A. Is the Risk addressed in a comprehensive manner?

The SRP believes that the Risk is addressed in a comprehensive manner and the ExMC Element is doing a good job in determining the tradeoffs to minimize the Risk.

B. Are there areas of integration across HRP disciplines that are not addressed that would better address the Risk?

The SRP thinks that the current integration between the ExMC Element and other HRP Elements is appropriate. The ExMC Element should be frequently updated on the research being done in all of the HRP Elements, and especially by HHC, since once these Risks are no longer research Risks and are ready to become medical Risks, they will fall under the ExMC Element.

The SRP recommends that the ExMC Element try to receive input and involvement from the flight surgeons office as early in the process as possible.

### **IV. Evaluation of the progress on the ExMC Research Plan since the 2014 SRP meeting**

Overall, the SRP was impressed with the many positive changes made to the ExMC Research Plan since the 2014 SRP review.

### **V. Additional Comments**

- Consideration should be given to more explicitly addressing astronaut selection to prevent risk. The actual level of health risk, given selection criteria, should be incorporated into improved specification of the IMM.

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- The current Path to Risk Reduction (PRR) addresses the Risk in two different ways: 1) It decreases likelihood (prevention) and 2) It decreases severity and consequences (enhanced medical capabilities). For condition-specific risks, this approach offers two different ways to decrease the risk burden. With the IMM model, risk mitigation can occur either by decreasing the likelihood and preventing risks from occurring or else by decreasing the morbidity of the risk through early diagnosis and treatment/rehabilitation. However, for other conditions that are either not part of the IMM list of 100 conditions or for which too little data are available for modeling, there can still be an unspecified level of medical risk present that cannot be quantified, predicted, or mitigated.
  - It would help to have realistic scenarios for mass, power, and volume (although they are uncertain) to assist with modeling efforts.
  - Focusing on the proving-ground paradigm is good, but NASA must be prepared for exploration missions.
  - The SRP believes that long-term health, i.e., lifetime health, is out of scope of this plan. Questions about lifetime health are basic research questions that lead to the creation of new knowledge. Questions about the exploration medical capability are applied research questions that lead to the creation of new operations, technologies, and systems. The expertise and methods needed to generate questions, conceptualize projects, and study lifetime health are different from those needed to predict and protect astronaut health during an exploration. Furthermore, how information about lifetime health would be used to design future missions is not clearly conceived. The SRP is concerned that studying lifetime health distracts the ExMC from its more urgent and essential goals.
    - One possibility is to carve out the Lifetime Health gap for assignment to a separate group or individual. A scientist focused on lifetime health among exploration astronauts needs a level of competency with epidemiologic methods used to study the long-term health effects of radiation; this is a specific set of competencies. Engineering expertise is not essential and is not well utilized in this work.

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## **VI. 2015 ExMC SRP Research Plan Review: Statement of Task for the Risk of Adverse Health Outcomes & Decrements in Performance due to Inflight Medical Conditions**

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The 2015 Exploration Medical Exploration (ExMC) Standing Review Panel (SRP) is chartered by the Human Research Program (HRP) Chief Scientist. The purpose of the SRP is to review the Risk of Adverse Health Outcomes & Decrements in Performance due to Inflight Medical Conditions (ExMC Risk) section of the current version of the HRP's Integrated Research Plan (IRP) which is located on the Human Research Roadmap (HRR) website (<http://humanresearchroadmap.nasa.gov/>). Your report, addressing each of the questions in the charge below and any addendum questions, will be provided to the HRP Chief Scientist and will also be made available on the HRR website.

### **The 2015 ExMC SRP is charged (to the fullest extent practicable) to:**

1. Based on the information provided in the current version of the HRP's IRP, evaluate the ability of the IRP to satisfactorily make progress in mitigating the Risk by answering the following questions:
  - A. Have the proper Gaps been identified to mitigate the Risk?
    - i) Are all the Gaps relevant?
    - ii) Are any Gaps missing?
  - B. Have the gap targets for closure been stated in such a way that they are measureable and closeable?
    - i) Is the research strategy appropriate to close the Gaps?
  - C. Have the proper Tasks been identified to fill the Gaps?
    - i) Are the Tasks relevant?
    - ii) Are there any additional research areas or approaches that should be considered?
    - iii) If a Task is completed, please comment on whether the findings contribute to addressing or closing the Gap.
  - D. If a Gap has been closed, does the rationale for Gap closure provide the appropriate evidence to support the closure?
2. Identify the strengths and weaknesses of the IRP, *and* identify remedies for the weaknesses, including, but not limited to, answering these questions:
  - A. Is the Risk addressed in a comprehensive manner?
  - B. Are there areas of integration across HRP disciplines that are not addressed that would better address the Risk?
  - C. Other
3. Based on the updates provided by the Element, please evaluate the progress in the research plan since the last SRP meeting.

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4. Please comment on any important issues that are not covered in #1, #2, or #3 above, that the SRP would like to bring to the attention of the HRP Chief Scientist and/or the Element.

**Additional Information Regarding This Review:**

1. Expect to receive review materials at least four weeks prior to the meeting.
2. Attend a meeting in Houston, TX on December 10 - 11, 2015.
  - A. Discuss the 2015 ExMC SRP Statement of Task and address questions about the SRP process.
  - B. Receive presentations from the HRP Chief Scientist (or his designee), the ExMC Element, and participate in a question and answer session, and briefing.
3. Prepare a draft final report (approximately one month after the meeting) that contains a detailed evaluation of the current IRP specifically addressing items #1, #2, and #3 of the SRP charge. The draft final report will be sent to the HRP Chief Scientist and he will forward it to the appropriate Element for their review. The ExMC Element and the HRP Chief Scientist will review the draft final report and identify any misunderstandings or errors of fact and then provide official feedback to the SRP within two weeks of receipt of the draft report. If any misunderstandings or errors of fact are identified, the SRP will be requested to address them and finalize the 2015 SRP Final Report as quickly as possible. The 2015 SRP Final Report will be submitted to the HRP Chief Scientist and copies will be provided to the ExMC Element and also made available to the other HRP Elements. The 2015 SRP Final Report will be made available on the HRR website (<http://humanresearchroadmap.nasa.gov/>).

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## VII. 2015 ExMC Standing Review Roster

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